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APPLICATION NUMBER:

75-456/458

MICROBIOLOGY REVIEW

OFFICE OF GENERIC DRUGS

HFD-620

Microbiology Review #1

August 2, 1999

A. 1. ANDA 75-456

APPLICANT: Abbott Laboratories/McPherson, KS2
1776 N. Centennial Drive
McPherson, KS 67460

2. PRODUCT NAME: Enalaprilat Injection

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: 1.25mg/mL,
carpuject (1mL fill in 2mL glass cartridge), IV use
only.

4. METHOD(S) OF STERILIZATION:

5. PHARMACOLOGICAL CATEGORY: Antihypertension agent

B. 1. DATE OF INITIAL SUBMISSION: ^{October 28} ~~September 4~~, 1998
Subject of this Review (Received ~~September 8, 1998~~ ^{October 30, 1998})

2. DATE OF AMENDMENTS:
10/28/98, 11/23/98, 5/7/99

3. RELATED DOCUMENTS:

4. ASSIGNED FOR REVIEW: July 27, 1999

C. REMARKS: This review was prepared by reviewing
the red copy (Chemistry section) of v. 1.1
and the blue copies (Archival section) of v.
1.2-1.4 and 2.1 of the ANDA.

The innovator product is marketed only
in vials. Abbott is marketing this product
in a syringe (carpuject).

D. CONCLUSIONS: The submission is recommended for approval on
the basis of sterility assurance. Specific
comments regarding the
process are provided in "E. Review Notes".

Lynne A. Ensor 8/2/99
Lynne A Ensor, Ph. D.

JAC 8/10/99

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micro Rev. 1

8/10/99

OFFICE OF GENERIC DRUGS

HFD-620

Microbiology Review #1

August 4, 1999

A. 1. ANDA 75-458

APPLICANT: Abbott Laboratories/McPherson, KS2
1776 N. Centennial Drive
McPherson, KS 67460

2. PRODUCT NAME: Enalaprilat Injection

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: 1.25mg/mL (1mL & 2 mL fills in 2mL vials), IV use only.

4. METHOD(S) OF STERILIZATION:

5. PHARMACOLOGICAL CATEGORY: Antihypertension agent

B. 1. DATE OF INITIAL SUBMISSION: ^{October 28}
~~September 4, 1998~~
Subject of this Review (Received ~~September 9, 1998~~
^{October 30})

2. DATE OF AMENDMENTS:
10/28/98, 11/23/98, 6/14/99

3. RELATED DOCUMENTS:

ANDA 75-456 - Abbott - Enalaprilat Inj.

4. ASSIGNED FOR REVIEW: July 29, 1999

C. REMARKS: This review was prepared by reviewing the red copy (Chemistry section) of v. 1.1, 1.2 & 2.1 and the blue copy (Archival section) of v. 1.3 & 1.4 of the ANDA.

The sterility assurance section submitted for this ANDA is very similar to that submitted for ANDA 75-456. Both ANDAs are for the production of Enalaprilat Injection (1.25mg/mL) by Abbott Laboratories, packaged in either a syringe (ANDA 75-456) or a vial (ANDA 75-458).

D. CONCLUSIONS: The submission is **recommended** for approval on the basis of sterility assurance. Specific comments regarding the aseptic filling process are provided in "E. Review Notes".

Lynne A. Ensor 8/4/99
Lynne A Ensor, Ph. D.

cc: 12.1

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